CLINICAL PRACTICE

ALERT

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Family PACT
Planning • Access • Care • Treatment
OFFICE OF FAMILY PLANNING
CALIFORNIA DEPARTMENT OF HEALTH SERVICES

INTRAUTERINE CONTRACEPTIVES (IUCs)

Family PACT (Planning, Access, Care, and Treatment) makes two Food and Drug Administration (FDA)-approved IUCs available: the copper T380A (ParaGard®) and the levonorgestrel releasing intrauterine system (LNG-IUS; Mirena®). Both IUCs are as effective as tubal sterilization, provide continuous contraceptive protection over long time intervals, allow for rapid return of fertility after removal, and have a high rate of client satisfaction. When compared with other methods over a five-year period, the IUC is the most cost effective method of contraception available.

KEY POINTS

- **IUCs are ideally suited for women who desire long-term contraception, including those who have not been pregnant and women who are unable or unwilling to use a combined hormonal method of contraception.**
- **An IUC user has no greater risk of pelvic inflammatory disease (PID) or tubal infertility than a woman who uses no method of contraception, other than a small transient increased risk of infection in the first few weeks after insertion. Studies confirm that women who currently do not have PID and do not engage in sexual behaviors that increase sexually transmitted infection (STI) risk are appropriate candidates for IUC use, regardless of age, parity, or a history of PID.**
- **Providers must include complete medical record documentation in a client's medical record to support services claimed for reimbursement. Providers should keep a written log or an electronic record of all IUCs inserted for at least three years from the insertion date including the client's name, medical record number, date of insertion, type of IUC, and the lot number of the IUC.**
- **All IUCs inserted through the Family PACT Program must be FDA-approved devices, labeled for use in the United States (U.S.), and obtained from an appropriately registered, permitted, or licensed manufacturer, wholesaler, or distributor. Providers must maintain invoices for IUCs billed to Family PACT for at least three years in accordance with Title 22, California Code of Regulations (CCR), Code 51476 (a).**

QUESTIONS AND ANSWERS

What are the main differences between the two available IUCs?

The copper IUC is FDA-approved for 10 years of use, while the LNG-IUS is approved for 5 years. The advantages of the copper IUC are the absence of hormonal side effects and a longer duration of efficacy. The advantages of the LNG-IUS are a reduction in dysmenorrhea, and after the first three months, shorter and lighter menstrual periods that may progress to amenorrhea.

When should an IUC be inserted?

A copper IUC can be inserted any time that there is reasonable assurance that the client is not pregnant, while LNG-IUS product labeling recommends insertion within seven days of the onset of menstruation. IUCs also can be inserted immediately after a delivery or pregnancy termination, although there is a slightly higher likelihood of expulsion after second trimester abortion and delivery.

What needs to be done prior to IUC insertion?

There are *no* routine screening tests recommended before IUC insertion. If clinically indicated, screening for chlamydia and gonorrhea may be performed before, or at the time of, IUC insertion. Pap smear frequency is not affected by IUC use, and a pre-insertion Pap smear, done in addition to routine Pap smears, is not recommended. Routine administration of prophylactic antibiotics has no effect on post-insertion infection rates and is unnecessary.

Who can insert IUCs in Family PACT?

Appropriately trained physicians, nurse practitioners, nurse midwives, and physician's assistants who are operating within their scope of practice can perform IUC insertions and removals in the Family PACT Program.

Can a woman who has never been pregnant choose to use an IUC?

Yes. Keep in mind that insertion may be more difficult in women who have never been pregnant and that expulsion rates are slightly higher.

Should a routine post-IUC insertion visit be scheduled?

Practices are inconsistent in the U.S., but the World Health Organization (and the package labeling for both IUCs) recommend a follow-up visit in three to six weeks or after the first menstrual period following insertion. A client who cannot feel her IUC string after her menstrual period should be advised to schedule a visit to confirm that the strings are visible and to exclude expulsion, pregnancy, or translocation.

What if an IUC user has a reading of "actinomyces-like-organisms" (ALO) on a Pap smear?

In most cases, ALO detected on Pap smear represents non-threatening *Actinomyces* colonization. However, this organism can cause pelvic actinomycosis, a very rare and poorly understood condition that causes pelvic pain similar to PID. The client should be evaluated by pelvic exam, but if tenderness and masses are absent, neither IUC removal nor antibiotic treatment is indicated.

Will Family PACT cover the LNG-IUS if it is being used mainly to treat heavy menstrual bleeding?

The LNG-IUS reduces menstrual bleeding and can be an effective treatment for menorrhagia. However, contraceptive methods provided in the Family PACT Program are intended to be used for family planning and not for treatment of unrelated medical conditions. As long as the primary purpose of the Mirena® IUC is contraceptive, it may be used in women with heavy menstrual periods.

APPLICATION OF FAMILY PACT STANDARDS

1. **Informed Consent**
   - All clients shall be advised of the availability of IUCs and offered this option in a non-coercive manner.
   - Consent shall be voluntary and the client may withdraw this consent at any time.
   - Parental consent is not required for provision of an IUC to a minor.
   - The consent process shall be provided verbally in language understood by the client and supplemented with written materials.
   - The client must sign a written consent for IUC insertion. The consent form provided by the IUC manufacturer is recommended but another with equivalent content may be used.
2. **Confidentiality**
   - IUC services shall be provided in a manner that respects the privacy and dignity of the individual client.
   - A confidential contact address should be obtained from the client so that she can be notified in the event of a product recall or other IUC-related safety considerations.
3. **Access to Care**
   - IUC insertion, follow-up visits, and removal shall be provided without cost to all Family PACT clients, either onsite or by referral.
4. **Availability of Covered Services**
   - IUC services may be provided onsite or by referral. The enrolled provider shall have an established referral arrangement with the other provider(s) when making referrals for these procedures.
   - The management of certain IUC complications is a benefit of Family PACT, as specified in the *Policies, Procedures, and Billing Instructions* (PPBI) manual. These services must be authorized and requested by the use of a Treatment Authorization Request (TAR).
   - To facilitate client contact in the case of a product recall, providers should keep a written log or electronic record of all IUCs inserted for at least three years from the insertion date. Include the client's name, record number, date of insertion, type of IUC, and the lot number of the IUC used.
   - All IUCs inserted through the Family PACT program must be FDA-approved devices, labeled for use in the U.S., and obtained from an appropriately registered, permitted, or licensed manufacturer, wholesaler, or distributor. Per Welfare and Institution Code, 14124.1, "Each provider, as defined in Section 14043.1, of health care services rendered under the Medi-Cal program or any other health care program administered by the department or its agents or contractors, shall keep and maintain records of each such service rendered, the beneficiary or person to whom rendered, the date the service was rendered, and such additional information as the department may by regulation require. Records herein required to be kept and maintained shall be retained by the provider for a period of three years from the date of the service." Providers must maintain invoices for IUCs billed to Family PACT for at least three years in accordance with Title 22, California Code of Regulations (CCR), Code 51476 (a).
5. **Scope of Clinical and Preventive Services**
   - Before insertion of an IUC, the clinician should perform a bimanual pelvic examination to determine the size, shape, and axis of the uterus, and to evaluate the presence or absence of pelvic tenderness. The IUC insertion kit should not be opened until the exam is completed and the client considered to be a candidate for insertion.
   - One reason that uterine sounding before insertion of either type of IUC is recommended in product labeling is to determine whether the uterine depth is between six and nine centimeters. The use of the IUC inserter *as the sound* may lead to the discovery of a uterine cavity that is too large or small to accommodate the IUC, and consequently, the contamination and wastage of the insertion kit.
   - Medical record documentation must support services claimed for reimbursement.
6. **Education and Counseling Services**
   - All staff performing education and counseling services shall be knowledgeable about IUCs and the policies for use under the Family PACT Program.
   - Specific instructions for the use of IUCs should be provided both verbally and in written form. Clients should be given the opportunity to ask questions and discuss personal concerns about IUCs, including the mechanism of action.
   - Clients shall receive education on protecting their reproductive health and plans for future pregnancy.

RESOURCES FOR INFORMATION ON INTRAUTERINE CONTRACEPTIVES

- Intrauterine Devices, in Hatcher RA, et al., Contraceptive Technology 18th Edition, 2004. Ardent Media.
- Intrauterine Contraception: The IUD, in Speroff L and Darney D, A Clinical Guide for Contraception, 4th Edition, 2005. Lippincott, Williams, and Wilkins.
- World Health Organization Medical Eligibility Guidelines: http://www.who.int/reproductive-health/publications/mec/.
- Mirena® Provider Web site: www.mirena-us.com (Healthcare Professionals section).
- ParaGard® Provider Web site: www.paragard.com.

PROGRAM POLICY

This alert provides an interpretation of the Family PACT Standards regarding intrauterine contraceptives into current practice: Providers should refer to the Family PACT PPBI manual for the complete text of the Family PACT Standards, official administrative practices and billing information. For the purposes of this and other Family PACT Clinical Practice Alerts, the term "shall" indicates a program requirement; the term "should" is advisory and not required.